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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/601,692	06/24/2003	Makiko Fliss	001107.00357	7618

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BANNER & WITCOFF, LTD.  
1100 13th STREET, N.W.  
SUITE 1200  
WASHINGTON, DC 20005-4051

EXAMINER
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FREDMAN, JEFFREY NORMAN

ART UNIT	PAPER NUMBER
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1637

MAIL DATE	DELIVERY MODE
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06/28/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Advisory Action</b> <b>Before the Filing of an Appeal Brief</b>	Application No.	Applicant(s)	
	10/601,692	FLISS ET AL.	
	Examiner	Art Unit	
	Jeffrey Fredman	1637	

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 18 June 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.  
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

#### AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);  
(b) ☐ They raise the issue of new matter (see NOTE below);  
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).


4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
5. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.  
6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
The status of the claim(s) is (or will be) as follows:  
Claim(s) allowed: \_\_\_\_\_  
Claim(s) objected to: \_\_\_\_\_  
Claim(s) rejected: 39, 40 and 119-125.  
Claim(s) withdrawn from consideration: \_\_\_\_\_

#### AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
10. ☒ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

#### REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.  
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). \_\_\_\_\_  
13. ☐ Other: \_\_\_\_\_

  
Jeffrey Fredman  
Primary Examiner  
Art Unit: 1637  
6/26/07

Continuation of 5. Applicant's reply has overcome the following rejection(s): The rejections under 35 U.S.C. 102 are overcome by the amendment, which will be entered..

Continuation of 11. does NOT place the application in condition for allowance because:

Applicant argues that the skilled practitioner will recognize the correction of deltaC302 as necessarily being deltaC303. Applicant has attached a declaration from Anirban Maitra. In assessing the weight to be given expert testimony, the examiner may properly consider, among other things, (1) the nature of the fact sought to be established, (2) the strength of any opposing evidence, (3) the interest of the expert in the outcome of the case, and (4) the presence or absence of factual support for the expert's opinion.

(1) In the instant case, the nature of the fact sought to be established is whether or not a skilled practitioner could determine, without ambiguity, that the deltaC 302 should have been delta C303. This is in a class of invention which the CAFC has characterized as "the unpredictable arts such as chemistry and biology." *Mycogen Plant Sci., Inc. v. Monsanto Co.*, 243 F.3d 1316, 1330 (Fed. Cir. 2001).

(2) There is significant evidence which opposes the conclusion of the Maitra declaration. Dr. Maitra argues that he "would have immediately noticed a run of the C nucleotides directly adjacent to position 302" and that such runs are notorious for polymerase slippage. Position 303 is clearly within the D-loop, the only other requirement imposed by the specification. So Dr. Maitra bases his position that 303 is the obvious correction based upon the presence of a run of C bases adjacent to position 302. Presumably this would represent a single typographical error of substituting a 2 for a 3 at the 3rd position in the number providing the location of the mutation. However, Dr. Maitra fails to recognize that position 312 in SEQ ID NO: 1 meets all of the same criteria. Position 312 is within the D-loop, position 312 would differ from 302 by a single typographical error of substituting a 0 for a 1 at the 2nd position, and the C in position 312 is part of a run of C nucleotides. In fact, looking at Table 1 of the Marchington reference cited by Dr. Maitra shows that position 312 is even within the D310 tract of Marchington. Thus, there is no way based upon the specification or the prior art for a skilled practitioner to determine if the deletion should have been at position 303 or 312. Because of a T at position 310, the C at position 303 and the C at position 312 are not equivalent. However, based upon the declaration of Dr. Maitra, there is no way for the "skilled practitioner" to distinguish which error was made, substituting a 2 for 3 at the 3rd' position, or substituting a 0 for a 1 at the second position. Either of these could have been the error and based upon the specification, it is impossible to tell which was the error. In fact, the specification at page 24 lists other deletion mutations, including a deletion of an A at position 2395. The sequence around the A deletion is ATCAaCCAAC where the A being deleted is in lower case. There is no run of A nucleotides as Dr. Maitra would indicate are commonly found. Following the narrowest, and most favorable interpretation to Applicant of this error, it is impossible to tell whether the mistake at position 302 should be 303 or 312, either of which represent a single typographical error and which share a run of C nucleotides. If we use the evidence of the other deletion at position 2395 to support the conclusion that a run of nucleotides is not required, then other possible C nucleotides which differ from position 302 by a single error include the C at position 332, the C at position 362 and the C at position 382.

(3) Dr. Maitra appears to have no direct interest in the case.

(4) There is little actual support for Dr. Maitra's position, given his failure to address the equivalence of position 312 and to appreciate that position 312 is equally likely as an error with position 303. Further, there is evidence based upon the specification to indicate that the error might also support finding the C might represent positions 332, 362 and 382, all of which represent a single change to the number 302. Therefore, given the strong data opposing the conclusion of Dr. Maitra, it is concluded that the error was not obvious, since there is no way to tell if the 302 should have been 303, 312, 332, 362 or 382. In particular, 303 and 312 share all of the same features identified by Dr. Maitra, but Dr. Maitra did not provide any reasoning to support selection of one of these positions over the other position.

Applicant's arguments directly track the Maitra declaration and are not found persuasive for the reasons given above.